

## REMARKS

Claims 42-44, 46-54, 56-64, 66-71 and 73-75 are pending.

### ***Rejections under 35 U.S.C. §112, first paragraph – new matter***

The Examiner has rejected claims 42-44, 46-54, 56-64, 66-71 and 73-75 under 35 U.S.C. §112, first paragraph as introducing new matter by reciting amino acids 108-188 of SEQ ID NO:2. As pointed out in Applicants' previous response, amino acids 108-188 of SEQ ID NO:2 correspond to the conserved domain found within PDGF/VEGF family members that contains 8 conserved cysteines. This conserved domain is discussed throughout the application. *See*, for example, page 2, lines 7-9; page 11, lines 15-17 and 26-30; page 53, lines 9-12; and Figures 3A-3B. However, the Examiner asserts that this disclosure is insufficient because "nowhere in the specification does it refer to this exact domain" and "Residues 80-188 neither end, nor begin, with cysteines" and because "it appears that this region contains 9 cysteines." Applicants respectfully traverse.

By asserting that "nowhere in the specification does it refer to this exact domain," The Examiner appears to require that the specification specifically contain, *verbatim*, the language "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2." Applicants respectfully disagree.

It is well established that an amendment to claim need not be supported verbatim in the specification. *See, e.g., ICN Photonics, Ltd. v. Cynosure, Inc.*, 73 F.3d 425 (Fed. Cir. 2003) ("Indeed, different language that expresses the same meaning found in the originally filed specification may be sufficient."), *citing Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). The test for determining whether or not a claim limitation added by amendment introduces new matter is whether "one skilled in the art, reading the original disclosure, [would] immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). *See also, Tronzo v. Biomet, Inc.* 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("[T]he missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure.") and *Fujikawa v. Wattanasin*, 93 F.3d at 1570 ("The disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.").

Applicants respectfully submit that the disclosure of the conserved domain found, for example, at page 2, lines 7-9; page 11, lines 15-17 and 26-30; page 53, lines 9-12; and Figures 3A-3B of the instant specification would "reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question," even though the language "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2" is not found in the specification *verbatim*. That is, the fact that the specification does not refer to the domain as "amino acids 108 to 188 of SEQ ID NO:2" does not render this claim limitation new matter.

The disclosure at page 11, lines 15-17 clearly indicates that "it is particularly important that all eight cysteines are conserved within all four members of the [PDGF/VEGF] family (see boxed areas of Figure 3)." Also at page 11, lines 26-30, the specification indicates that "active fragments are meant to include any portions of the full length amino acid sequence which have less than the full 419 amino acids of the full amino acid sequence as shown in SEQ ID NO:2, ***but still contain the eight cysteine residues shown conserved in Figure 3.***" Thus, a skilled artisan would easily recognize the importance of the conserved 8 cysteine domain. Upon comparing Figure 3 and SEQ ID NO:2, one of skill in the art could readily determine the amino acid numbering (in SEQ ID NO:2) of the eight boxed cysteine residues shown in Figure 3, i.e., the conserved cysteines correspond to amino acid residues 108, 133, 139, 142, 143, 150, 186 and 188. Thus, the conserved domain spans amino acid residues 108 to 188 of SEQ ID NO:2. Thus, one of skill in the art would clearly understand that Applicants' had possession of the subject matter in question.

Applicants are confused as to the Examiner's assertion that "[r]esidues 80-188 neither end, nor begin, with cysteines." The claims do not recite "residues 80-188." However, Applicants will respond to this rejection assuming that the Examiner meant to refer to "residues 108-188." As enumerated above, when the boxed cysteine residues of Figure 3 are matched with the corresponding residues of SEQ ID NO:2, the conserved 8 cysteines correspond to amino acid residues 108, 133, 139, 142, 143, 150, 186 and 188. Thus, contrary to the Examiner's assertion "[r]esidues 108-188" do begin and end with cysteines.

Furthermore, the fact that this region may include 9 cysteines is not relevant to the inquiry of whether or not one of skill in the art would understand that Applicants' had possession of the claimed subject matter. Figure 3 clearly indicates the 8 conserved cysteine residues. One of skill in the art would therefore understand what is meant by "the conserved 8 cysteines" even

if the domain spanning amino acid residues 108-188 of SEQ ID NO:2 contains 9 cysteines. The 9<sup>th</sup> cysteine, found at amino acid residue 114 of SEQ ID NO:2 is not boxed in Figure 3.

For the reasons provided above, Applicants respectfully submit that the claims, as previously pending did not introduce new matter. However, in the interest of advancing prosecution, Applicants have amended claim 42 to recite "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2, which includes the eight conserved cysteines at amino acids 108, 133, 139, 142, 143, 150, 186 and 188" to further clarify the location of the conserved 8 cysteine amino acid residues. Applicants respectfully request withdrawal of this rejection.

### **CONCLUSION**

The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application. Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: Oct 12, 2004

Respectfully submitted,

By   
Melissa Jean Pytel

Registration No.: 41,512  
HUMAN GENOME SCIENCES, INC.  
14200 Shady Grove Road  
Rockville, Maryland 20850  
(301) 610-5764

MMW/MJP/ba